K130055

510(k) SUMMARY

FEB 14 2013

1. Date: February 1, 2013

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
South China University of Technology
Guangzhou, P.R. China 510641

3. Contact person: Joe Shia
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4. Device Name: Wondfo Buprenorphine Urine Test
Classification: Class II

Product Code	Regulation Name	CFR #
DJG	Opiate Test System	21CFR 862.3650

5. Predicate Devices: K113624
Guangzhou Wondfo Biotech
Wondfo Buprenorphine Test

6. Intended Use

Wondfo Buprenorphine Urine Test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a cutoff concentration of 10 ng/mL. The test is available in a dip card format and a cup format. It is intended for over the counter use.

The Buprenorphine assay will yield preliminary positive results when Buprenorphine is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for buprenorphine in urine. The Wondfo Buprenorphine Urine Test shows the drug was or was not present at the cutoff level. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

The device does not differentiate between drug abuse and prescription use of buprenorphine.

7. Device Description

Immunochromatograph assays for Buprenorphine Urine Tests use a lateral flow, one step system for the qualitative detection of Buprenorphine (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes.

8. Substantial Equivalence Information

Item	Device	Predicate
Indication(s) for use	For the qualitative determination of Buprenorphine in human urine.	Same
Calibrator	Buprenorphine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type Of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	10ng/ml	Same
Configurations	Cup, dip card	Same
Intended Use	OTC Use	Prescription Use

9. Standard/Guidance Document Reference

- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
- Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elservier Science Publishing Company, Inc., New York, 1988
- Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.
- Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
- Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.

10. Test Principle

It is a rapid test for the qualitative detection of Buprenorphine in urine samples. It is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentration below the target cut off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device.

This produces a colored test line that indicates a negative result. When analyte concentration is above the cutoff, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in the test region, indicating a potentially positive result.

11. Performance Characteristics

1. Analytical Performance

   Clearance of candidate device is for addition of OTC claim. See analytical performance in predicate k113624.

2. Comparison Studies

   See studies in predicate k113624

Lay-user study

Test Cup format:

A lay user study was performed at three intended user sites with 140 lay persons. Participants in the study were 68 females and 72 males tested the Buprenorphine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with a package insert, 1 blind labeled sample and a device. The results are summarized below.

Concentration	Number of samples	OTC user		%Agreement With GC/MS
		Positive	Negative	
Negative	20	0	20	100
-75% Cutoff	20	0	20	100
-50% Cutoff	20	0	20	100
-25% Cutoff	20	2	18	90.0
+25% Cutoff	20	19	1	95.0
+50% Cutoff	20	20	0	100
+75% Cutoff	20	20	0	100

Dip Card format:

A lay user study was performed at three intended user sites with 140 lay persons. Participants in the study were 71 females and 69 males tested the Buprenorphine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with a package insert, 1 blind labeled sample and a device. The results are summarized below.

Concentration	Number of samples	OTC user		%Agreement With GC/MS
		Positive	Negative	
-100% Cutoff	20	0	20	100

-75% Cutoff	20	0	20	100
-50% Cutoff	20	0	20	100
-25% Cutoff	20	2	18	90.0
+25% Cutoff	20	20	0	100
+50% Cutoff	20	20	0	100
+75% Cutoff	20	20	0	100

3. Clinical Studies

   Not applicable

12. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that Wondfo Buprenorphine Urine Tests are substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

Guangzhou Wondfo Biotech Co., Ltd.
c/o Joe Shia
LSI International Inc.
504 East Diamond Ave, Suite F
Gaithersburg, MD 20878

Re: k130055
Trade/Device Name: Wondfo Buprenorphine Urine Test
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG
Dated: January 09, 2013
Received: January 11, 2013

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (K130055):

Device Name: Wondfo Buprenorphine Urine Test

Indications for Use:

Wondfo Buprenorphine Urine Test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a cutoff concentration of 10 ng/mL. The test is available in a dip card format and a cup format. It is intended for over the counter use.

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The device does not differentiate between drug abuse and prescription use of buprenorphine.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use _X_ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.02.13 08:54:16 -05'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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